

REMARKS**Status of Claims**

In this paper, claims 1-11, 13, and 18-20 have been cancelled without prejudice or disclaimer. Claims 12, 14, 15-17, 21 and 22 have been amended. Support for the amendments can be found in the specification and claims as filed, e.g., at page 43, lines 9-18. Claims 15-17, 21 and 22 stand withdrawn from consideration. Claims 12, 14-17, 21 and 22 are pending, and claims 12 and 14 are presently under examination. No new matter has been added.

The amendments to and/or cancellation of the claims are being made for the purpose of expediting prosecution and are made without prejudice or waiver of any subject matter thereof. Applicants reserve the right to present the original claims in this or a continuing application.

Double Patenting Rejections

In the Office Action, claims 1-12 and 14 were rejected on the ground of non-statutory obviousness-type double patenting over the claims of U.S. Patent Nos. 6,974,806, 5,482,967, and 5,700,810. This rejection is traversed.

Without agreeing with the rejection, claims 1-11 have been cancelled, and the rejection of these claims is moot. As to claims 12 and 14, Applicants contend that the presently-claimed subject matter is not obvious over the claims of the cited patents.

In order to support an obviousness-type double patenting rejection, the Office must show:

(A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and

(B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the patent.

MPEP 804(II)(B)(1).

However, “[w]hen considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.” Id. (citation omitted)

Although the Office Action states that claims 12 and 14 are not patentably distinct over the claims of the cited patents, Applicants point out that there is no disclosure in the claims of the reference patents of the particular salt forms of the compound as presently claimed. Moreover, the Office Action does not specifically point to anything in the claims of the reference patents that renders obvious the specific salt forms of the compound of the pending claims, and Applicants contend that the pending claims are not obvious in view of the cited claims of the reference patents.

In the Office Action, claims 1-12 and 14 were provisionally rejected on the ground of non-statutory obviousness-type double patenting over the claims of co-pending application nos. 10/500,839, 11/212,800, and 11/728,550. This rejection is traversed.

As an initial matter, Applicants point out that application nos. 10/500,839 and 11/728,550 are abandoned, and no double patenting rejection can be made over these abandoned applications.

As to USSN 11/212,800, Applicants point out that there is no disclosure in the pending claims of the reference application of the specific salt forms of the compound as presently claimed. Moreover, the Office Action does not specifically point to anything in the pending claims of the reference application that renders obvious the specific salt forms of the compound of the subject pending claims, and Applicants contend that the pending claims are not obvious in view of the claims of the reference application.

Furthermore, Applicants respectfully request that any provisional double patenting rejections be deferred until the present application is otherwise in condition for allowance.

Reconsideration and withdrawal of the rejections is proper and the same is requested.

Rejection under 35 U.S.C. §112, second paragraph

Claim 1 and claims dependent therefrom stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. This rejection is traversed.

Without agreeing with the rejection, and merely to expedite prosecution of the present application, claim 1 has been cancelled without prejudice or disclaimer. Moreover, the language to which the Examiner objected is not found in the pending claims.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. §103(a)

In the Office Action, claims 1-12 and 14 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent Nos. 5,482,967 (“the ‘967 patent”) and 5,700,810 (“the ‘810 patent”). This rejection is traversed.

As noted above, without agreeing with the rejection, to expedite prosecution of the present application, claims 1-11 have been cancelled without prejudice or disclaimer.

Claim 12, as now pending, is directed to two specific salt forms of a single compound. As disclosed in the present application, these two salt forms (referred to Compounds A and B in Experimental Example 1 at page 114 of the specification) have superior oral absorbability compared to the absorbability of the free acid form (Compound X of Experimental Example 1). These unexpectedly superior properties are not taught or suggested by the ‘967 and/or ‘810 patents, whether taken alone or in combination. Although the Office Action alleges that “[a]nalog design to modify solubility properties is routine to one of ordinary skill in the art of medicinal chemistry” (Office Action at pages 5-6), the cited patents provide no motivation to make the particular claimed salt forms of claim 12. Applicants contend that the pending claims are patentable over the ‘976 and ‘810 patents.

Reconsideration and withdrawal of the rejection is proper and the same is requested.

Rejoinder of withdrawn claims

As noted above, claims 15-17, 21 and 22 stand withdrawn from consideration. Applicants respectfully submit that rejoinder of claims 15-17, now written as pharmaceutical composition claims and dependent upon claim 12, should not impose an undue burden. Additionally, significant expense and time would be saved if these claims are searched and examined at this time.

In addition, Applicants contend that examination of claims 15-17, 21 and 22 is proper under the examination practice outlined in MPEP 1893.03(d). The present application is the U.S. national phase under 35 U.S.C. 371 of PCT/JP05/03838, as acknowledged in the Office Communication (restriction requirement) dated March 3, 2008. Under the unity of invention standard applicable to U.S. national phase applications under 35 U.S.C. 371, Applicants are entitled to examination of claims forming a single inventive concept. Applicants contend that the pending claims are linked to form a single general inventive concept because there is a technical relationship among the pending claims that involves at least one common or corresponding special technical feature (e.g., the compounds of claim 12). Applicants submit that examination of all pending claims is appropriate and such action is requested.

Finally, even under restriction practice pursuant to 37 C.F.R. 1.141-1.146, rejoinder of method claims (where restriction was required between a product and a process of making and/or using the product) is appropriate when the product invention is elected and subsequently found allowable, and all claims to the nonelected process invention depend from or otherwise require all the limitations of an allowable claim. See, e.g., MPEP 821.04. Pending method claims 21 and 22 each depend from or otherwise require all the limitations of claim 12 (which, as discussed herein, is allowable). Applicants therefore request rejoinder and consideration of claims 21 and 22.

CONCLUSION

For at least the foregoing reasons, Applicants contend that the application is in condition for allowance. Early and favorable consideration of the application is earnestly solicited.

If the Examiner considers that obstacles to allowance still exist, the undersigned invites the Examiner to contact him at the telephone number given below.

In the event that any extension of time is required, the undersigned conditionally requests any necessary extension. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Reference No. 66043 (70820), Customer No. 21874.

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Respectfully submitted,

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